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TITLE: Remote Interactive Monitoring of Patients on
Anticoagulant Therapy to Improve Outcome and Avoid
Complications

PRINCIPAL INVESTIGATOR: Jennifer L. Calagan, Ph.D., M.D.

CONTRACTING ORGANIZATION: Walter Reed Army Medical Center
Washington, DC 20307-5001

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MidTerm Overall Evaluation Report

PROPOSAL: 1999000211

TITLE: Remote Interactive Monitoring of Patients on Anticoagulant Therapy to Improve Outcome and Avoid Complications

1. ACCOMPLISHMENTS:

The research protocol under which the project will be accomplished has been developed, consent form generated, data collection forms designed and all have been approved pending final minor revisions by Department of Clinical Investigation including Human Use committee. Cooperative agreement has been developed with Health Hero Network to provide equipment and technical support for the project at no charge to the government except for lost equipment. The project director has been identified and is working with the project. Statement of Work/Job description has been generated for the project Nurse Practitioner and hiring action will be undertaken. A physical location in which to base the project and personnel has been identified and is ready for use. Initial equipment needs have been identified and prioritized and acquisition is imminent. A PhD candidate in Public Health Program with an emphasis on Health Care Systems and who has computer database and statistical design expertise has joined the project. Outcomes measurement parameters have been defined and statistical work has begun.

2. PROBLEMS:

Because of required major changes to the protocol to which this project was attached, complete revision/rewrite of the protocol, all data forms, and consent form, the project had to be resubmitted to the Department of Clinical Investigation essentially de novo and the complete approval process, not merely amendment, had to be accomplished. The cooperative agreement with HealthHero Network, which is a significant financial advantage to the government (equipment will be loaned rather than purchase with support included), had to be developed. Position requirements for the project had to be developed. The above were all accomplished but significant time was required. As a result, however, the project has been developed essentially as described in the proposal.

3. LIFE-CYCLE:

Once required revisions to the protocol and consent forms are given final approval, enrollment can begin as described in the original project plan. Data collection forms may be revised or appended in such a way as to allow reduction of the responses to a statistical database which will better allow outcomes evaluation with statistical analysis, economic analysis. Exact mechanisms with statistical tools for participant selection, processing and data collection are being developed. HealthBuddy dialogs which may now allow patients to report their PST-INR results or visits to the lab have to be finalized and programmed. Supplies of HealthBuddies and PST units have to be received to the designated project site. Some troubleshooting of the PST equipment procedures needs to be done with ITC, the makers of the approved unit.

4. DELIVERABLES:

Outcomes measured will primarily be: 1-Quality of Care 2-Access to Care 3-Acceptance of Care/patient satisfaction 4-Cost to Government Statistical tools to analyze these have been/are being developed. Parameters which will be databased are patient demographics as allowed and 1-complications detected complications possibly averted time spent with INR in range of target and time to target 2-time required to reach specified benchmarks: time to obtain lab result time to reach coumadin clinic personnel time to receive dose adjustment instructions 3-patient surveys clinician surveys 4-documented costs of tests needed or avoided cost of time for active duty personnel lost to duty hospitalization-costs needed or avoided Many costs are published, catalogued or calculable from known data (salary for active duty of given rank, charge for test, historic cost of day's hospitalization). These will be collected in demographic surveys and from published data. These findings are applicable Amedd-wide as coumadin patients might be managed from a central location instead of on the economy, and avoided time lost to duty or hospitalizations would save

money for both medical facilities and the patient's unit.